REMARKS

Claims 1 and 5-11 are in the case and presented for reconsideration. Claim 4 has been canceled. Claim 1 has been amended. No new matter has been added.

Claims 1 and 4-9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,971,394 (Silwa) in view of U.S. Patent No. 5,331,947 (Shturman). Claims 10 and 11 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,971,394 (Silwa) in view of U.S. Patent No. 5,331,947 (Shturman) and further in view of U.S. Patent No. 6,004,269 (Crowley et al.).

Sliwa, Jr. et al. is directed to methods and devices for ablation wherein some embodiments disclose a device 400 that delivers focused ultrasound formed at an angle of 10 to 170 degrees, more preferably, 30 to 90 degrees and more preferably about 60 degrees as defined relative to a focal axis A. Column 28, lines 33-42. Although Sliwa, Jr. et al. discloses the use of a multi-element acoustic phased array, there are no specific teachings or even suggestions relating to the number of ultrasound transducers nor a range of azimuths associated with the delivery of ultrasound energy therefrom. See also the Examiner's admission in Par. No. 9 of the Final Rejection dated September 5, 2006 that Sliwa, Jr. et al. is clearly "silent" regarding a range of azimuths such as found with Applicant's claimed present invention. Moreover, Sliwa, Jr. et al. is also particularly vague and lacks any particular guidance to one of ordinary skill in this field as to the number of ultrasound transducers that would be useful (and successful) for an ultrasound ablation in the pulmonary vein adjacent the delicate phrenic nerve.

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

As clearly taught in Sliwa, Jr. et al. "focused ultrasound...forms an angle of 10 to 170 degrees, more preferably 30 to 90 degrees and most preferably about 60 degrees ...." Col. 28, Lines 39 – 42.

Furthermore, although Sliwa Jr. et al. does mention avoiding damage to delicate structures in the heart, such as the phrenic nerve, as pointed out by the Examiner, it is clear that Sliwa Jr. clearly teaches that it is essential to avoid "endocardial devices" and the venous system which is completely divergent from Applicant's claimed present invention as amended.

Particularly, Sliwa Jr. et al. teaches:

> Finally, the heat generated by endocardial devices which flows outward *through the myocardium cannot be precisely controlled and can damage extracardiac tissues such as the pericardium, the phrenic nerve and other structures*. What are needed, therefore, are devices and methods for forming lesions that isolate the pulmonary veins from the surrounding myocardium which overcome these problems. *The devices and methods will preferably be utilized epicardially to avoid the need for access into the left chambers of the heart and to minimize the risk of producing thrombus*. (emphasis added) Col. 2, Lines 19-30.

Additionally, Sliwa Jr. et al. clearly teaches at Col. 17, Lines 22-28 that its device is strictly limited to an epicardial (non-venous approach), where it states:

> When inflated, balloon 150 engages the inner surface of the pericardium P and urges inner probe 74 against the epicardial surface of heart H. This ensures close contact between electrodes 76 and the epicardium, and protects extracardiac tissue such as the pericardium and phrenic nerve from injury caused by the ablation probes.

Thus, one of ordinary skill in the ablation field would be entirely discouraged from following the path set out in the teaching Sliwa, Jr. et al. Accordingly, it is clear that this reference actually teaches away from Applicant's claimed present invention as amended.

Shturman teaches an inflatable sheath for introduction of ultrasonic catheter through the lumen of a fiber optic endoscope that does mention that its ultrasound array can contain 32 or 64 transducers. However, there is nothing further in this reference (thereby constituting a reference with very limited teachings) that would ever lead one of ordinary skill in this field to arrive at Applicant's claimed present invention, especially when combined with Sliwa, Jr. et al., since the teachings of Sliwa, Jr. et al. are in a completely divergent path from that set forth in Applicant's claimed present invention.

Crowley et al. teaches catheters for imaging, sensing electrical potentials, and ablating tissue wherein its catheter includes an ultrasound device 10 for acoustic imaging. It is important to note that Crowley et al. does not specifically teach external imaging capability such as found with Applicant's claimed present invention of Claims 10 and 11, but rather, Crowley et al. specifically teaches classic electrophysiological mapping using a standard mapping electrode adjacent its ultrasound transducer at the distal end of its catheter 10. See Col. 3, Lines 52 – 57. Thus, Crowley et al. is clearly of limited scope and content when compared to Applicant's claimed present invention.

Furthermore, as is well established, prior art patents can only be used for what they clearly disclose or suggest. *In re Randol and Redford*, 425 F. 2d 1268, 165 USPQ 586, 588 (C.C.P.A. 1970). And, as set forth in *In re Randol and Redford*, it is clearly improper to use a patent as a reference for modifying its structure in a manner in which the prior art references do not suggest. Thus, just because Crowley discloses electrophysiological mapping using a mapping electrode adjacent its ultrasound transducer, it does not mean that unreasonable license should be taken with the teachings of this reference as proposed by the Examiner, i.e. an unreasonable attempt to modify this teaching in an effort to arrive at the Applicant's claimed present invention, especially when there is absolutely no indication in the limited teachings of Crowley et al. that such a modification (as suggested by the Examiner) could ever be feasible or even desirable.

Therefore, it is clear that these prior art references (Sliwa Jr. et al., Shturman and Crowley et al.) are being improperly applied by the Examiner, using hindsight reconstruction to

pick and choose elements from these references, in the face of a contrary teaching in each of these references.

The PTO has the burden under section 103 of establishing a *prima facie* case of obviousness. This burden can only be satisfied by a legal conclusion based on underlying factual inquiries. See *KSR Int'l Co. v. Teleflex, Inc.,* 550 U.S., 82 USPQ2d 1389 (2007). Accordingly, it is clear that these references are of limited scope and content and provide teachings that are significantly different from Applicant's claimed present invention.

Accordingly, by this Amendment and for the reasons outlined above, Applicant's claimed present invention is neither anticipated by nor rendered obvious by the cited prior art references and favorable action is respectfully requested.

Respectfully submitted,

By: /Louis J. Capezzuto/
Louis J. Capezzuto
Reg. No. 37,107

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2218
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